

Remarks

Claims 1-38 remain pending in the present application. Claims 1-6 are examined after a Restriction Requirement, and claims 7-38 are withdrawn as non-elected. With the cancellation of claim 2, claims 1 and 3-38 are pending.

Descriptive support for the insertion of “wherein the morphotes exhibit tissue-level multicellular self-organization into a multicellular, mammalian tissue-like pattern when cultured in vitro” in claim 1 can be found in the specification at page 1, line 23.

Claim Rejections -- 35 U.S.C. 101

Applicant respectfully traverse the rejection of claims 1-6 under 35 U.S.C. 101 as directed to non-statutory subject matter.

The Office Action rejects claims 1-6 as directed to non-patentable subject matter because the Office Action asserts that the culture of morphotes according to claims 1-6 have the same characteristics and utility as morphotes found naturally. Applicant disagrees. Claims 1 and 3-6 are directed to a culture of morphotes derived from mammalian tissues. According to the specification, the culture of morphotes exhibit

(A) morphological characteristics of both prokaryotic and eukaryotic cells, including resemblance to prokaryotic cells at the unicellular level; and

(B) an ability of tissue-level multicellular self-organization into a multicellular mammalian tissue-like pattern when cultured in vitro, wherein the multicellular mammalian tissue-like pattern can be:

(a) sheet-like tissue-level multicellular self-organization when cultured in vitro;

(b) capillary-like-tissue-level multicellular self-organization when cultured in vitro; or

(c) trabecular (spongy) bone-like tissue-level multicellular self-organization when cultured in vitro

(see the specification in page 1, line 20 to page 2, line 4; page 6, lines 1-8).

In some of the embodiments of the culture of morphotes of the claimed invention, the morphotes connect or interconnect into networks of varying densities, scales, or dimensions that tessellate triangular, quadrilateral, and polygonal areas or shapes that contain no morphote cells (see the specification, page 6, lines 8-11).

Since cells found in nature do not have the characteristics of the culture of morphotes of claims 1 and 3-6, applicant contends that the culture of morphotes of claims 1 and 3-6 are not any products of nature. In contrast, the culture of morphotes of claims 1 and 3-6 are made by humans. As a result, claims 1 and 3-6 are directed to patentable subject matter.

Claim Rejection -- 35 U.S.C. 112, First Paragraph

Applicant respectfully traverses the rejection of claims 1-6 for failing to comply with the written description requirement. The Examiner rejected claims 1-6 for failing to comply with the written description requirement because the scope of the claims includes numerous structural variants without any disclosure of the distinguishing attributes shared by the members of the genus, and yet the specification discloses only one species (the culture of morphotes isolated by the method of Example 1) of the broad genus. The Examiner took a position that the culture of morphote of Example 1 is insufficient to describe the genus. Applicant disagrees.

The Examiner asserted that the specification does not disclose any distinguishing attributes shared by the members of the genus. The assertion is not true because the specification discloses that the morphote cultures of the invention exhibit distinguishing attributes shared by the members of the genus: resembling prokaryotic cells at the unicellular level with the ability to self-organize *in vitro* into multicellular, mammalian eukaryotic tissue-like patterns, wherein the patterns can be tissue-like sheets, capillary-like networks, and trabecular bone-like structures (e.g., see paragraph [0003]). The culture of morphotes shown in Example 1 exemplifies the genus, and along with the general

description of the characteristics shared by members of the genus, lets a person skilled in the art recognize that applicant had possession of the genus according to claims 1 and 3-6 at the time the instant patent application was filed.

The Examiner also asserted that the culture of morphotes according to the claims are analogous to Example 17 in the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph's written description requirement because the product of Example 17 is identified via a method of production. Applicant disagrees. The claims of Example 17 are directed to methods, while the pending claims 1-6 are directed to a product, i.e., a culture of morphotes. Specifically, claim 1 of Example 17 is directed to a method for the selective inhibition of POPKIN-2 in a patient comprising administering a compound that selectively inhibits activity of the POPKIN-2 enzyme. The analysis of the Guidelines states that the method requires a selective inhibitor of the POPKIN-2 enzyme to practice the invention, and yet the specification does not describe an actual reduction to practice of the method and does not describe the complete structure of a compound that selectively inhibits POPKIN-2 activity. In contrast, in the pending patent application, the specification describes an actual reduction to practice of the culture of morphotes in Example 1, and describes the structural characteristics of the culture of morphotes. Thus, the Office Action erred in asserting that Example 17 in the Guidelines is analogous to the culture of morphotes claimed in the pending patent application.

Withdrawal of the lack of written description requirement is requested.

Claim Rejection -- 35 U.S.C. 112, Second Paragraph

Applicant respectfully traverses the rejection of claims 1-6 as being vague because of the word "derived." Without acquiescence with the rejection, applicant has replaced "derived" with "obtained" in claim 1. A person skilled in the art would understand the recitation, "obtained from mammalian tissue," to mean that the culture of morphotes is originated from the mammalian tissue. The word "obtained" is not vague.

Claim Rejections -- 35 U.S.C. 102(b)

I. Applicant respectfully traverses the anticipatory rejection of claims 1-6 over Wainwright (*Medical Hypotheses*, vol. 60, pp. 290-292, Feb. 2003). The Examiner asserted that Wainwright discloses the culture of morphotes of claims 1-6 because the term “morphote” is defined as pleomorphic organisms which exhibit morphologic and genetic characteristics of both prokaryotic and eukaryotic cells, and Wainwright isolated a culture of bacteria (prokaryotic) from mammalian tissue, which superficially appeared fungal (eukaryotic). Applicant disagrees.

The cancellation of claim 2 renders its rejection moot. Wainwright fails to anticipate claims 1 and 3-6 because the organism isolated by Wainwright merely superficially appeared fungal under low magnification. However, Wainwright concedes that, under higher magnification (1000x), the isolated organism is observed to comprise bacterial rods, some exhibiting long bacterial filaments rather than fungal mycelium (p. 290, right column, lines 5-17 and Figure 1). Wainwright stated that: “The branched CD form is clearly bacterial and not fungal in nature” and the branched CD form is identified as *Bacillus licheniformis* (see p. 290, right column, lines 19-21). In other words, the organism isolated by Wainwright is actually a bacteria and does not have fungal morphology. Thus, the Examiner was incorrect in characterizing the organism isolated by Wainwright as having characteristics of eukaryotic cells. Wainwright does not disclose an culture of morphotes. As a result, claims 1 and 3-6 should not be rejected over Wainwright.

Furthermore, Wainwright fails to anticipate claims 1 and 3-6 because the organism isolated by Wainwright

(a) does not exhibit tissue-level multicellular self-organization into a multicellular, mammalian tissue-like pattern when cultured in vitro as recited in claim 1;

(b) does not exhibit sheet-like tissue-level multicellular self-organization cultured in vitro as recited in claim 3;

(c) does not exhibit capillary-like tissue-level multicellular self-organization when cultured in vitro;

(d) does not exhibit trabecular (spongy) bone-like tissue-level multicellular self-organization when cultured in vitro; or

(e) three or more of the organism isolated by Wainwright do not connect or interconnect into networks of varying densities, scales, or dimensions that tessellate triangular, quadrilateral, and polygonal areas or shapes that contain no morphote cells.

II. Applicant respectfully traverses the anticipatory rejection of claims 1-6 over Robinson. The Examiner asserted that Robinson discloses the culture of morphotes according to claims 1-6 because Robinson isolated a culture of pleomorphic bacterium (prokaryotic) from mammalian tissue, which also expressed both human genes/proteins (eukaryotic). Applicant disagrees. The cancellation of claim 2 renders its rejection moot.

Robinson isolated a culture of bacteria that showed fungal-like morphology (see Figure 1c). However, the culture of morphotes of the invention resembles eukaryotic cells at the multicellular level due to their ability to self-organize into multicellular, **mammalian tissue-like patterns** (see the first paragraph of the Detailed Description of the Invention in page 6 of the specification). The fungal-like morphology of the culture of bacteria isolated by Robinson does not mean that the culture of bacteria isolated by Robinson resembles eukaryotic cells at the multicellular level due to their ability to self-organize into multicellular, **mammalian tissue-like patterns**. Thus, claims 1 and 3-6 should not be rejected as anticipated by Robinson.

Furthermore, Robinson fails to anticipate claims 1 and 3-6 because the bacteria isolated by Robinson

(a) does not exhibit tissue-level multicellular self-organization into a multicellular, mammalian tissue-like pattern when cultured in vitro as recited in claim 1;

(b) does not exhibit sheet-like tissue-level multicellular self-organization cultured in vitro as recited in claim 3;

(c) does not exhibit capillary-like tissue-level multicellular self-organization when cultured in vitro;

(d) does not exhibit trabecular (spongy) bone-like tissue-level multicellular self-organization when cultured in vitro; or

(e) three or more of the bacteria isolated by Robinson do not connect or interconnect into networks of varying densities, scales, or dimensions that tessellate triangular, quadrilateral, and polygonal areas or shapes that contain no morphote cells.

Withdrawal of the anticipatory rejections is requested.

In the event that the filing of this Response is not timely, applicant petitions for an appropriate extension of time. The Examiner is invited to contact the undersigned at (202) 220-4200 to discuss any matter concerning this application. The Office is authorized to charge any fees related to this communication to Deposit Account No. 11-0600.

Respectfully submitted,

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